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10/034,336	12/28/2001	Gopinathan K. Menon	680.0049USU	8349

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EXAMINER

COE, SUSAN D

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 05/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/034,336

Applicant(s)

MENON ET AL.

Examiner

Susan Coe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 17-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. The amendment filed February 10, 2003, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.
2. Claims 1-30 are pending.
3. In Paper No. 6, dated October 21, 2002, applicant's elected with traverse of Group I, claims 1-16.
4. Claims 17-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 6.
5. Claims 1-16 are examined on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-3, 6, 7, 14, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 5,910,308.

Applicant's claims are drawn to a skin composition comprising *Gynostemma*.

US '308 teaches a cosmetic composition that contains *Gynostemma*. The *Gynostemma* is present from 10 to 30 percent and contains numerous carriers (see claims).

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7. Claims 1 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Japanese Pat. Appl. No. 2000128729 A.

Applicant's claims are drawn to a skin composition comprising *Rhodiola*.

JP '729 teaches a cosmetic composition that contains *Rhodiola*.

8. Claims 1, 2, 8, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 5,660,840.

Applicant's claims are drawn to a skin composition comprising coconut water.

US '840 teaches a cosmetic composition comprising 50% coconut milk. Coconut milk appears to be the same as coconut water.

9. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Japanese Pat. Appl. No. 200014498 A.

Applicant's claims are drawn to a skin composition comprising neem extract.

JP '498 teaches a cosmetic composition that contains neem extract.

Claim Rejections - 35 USC § 103

10. Claims 1-7, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '308.

As stated above, US '308 teaches a cosmetic that contains *Gynostemma*. However, the reference does not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It

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would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

The reference also does not specifically teach adding all of the additional ingredients in claim 14. However, all of these ingredients are known in the art to be suitable for adding to a topical composition. Therefore, a person of ordinary skill in the art would have been motivated to add these ingredients to the composition taught by the combination of the references.

The reference does not specifically teach formulating the composition in the forms claimed by applicant in claim 15. These forms of administration are well known in the art to be acceptable forms for a topical composition. Based on this knowledge, a person of ordinary skill in the art would have had a reasonable expectation that formulating the composition taught by the reference in the claimed forms would be successful. Therefore, an artisan of ordinary skill would have been motivated to formulate the composition taught by the reference in the forms claimed by applicant.

11. Claims 1-5, 11, 12, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP '729.

As stated above, US '729 teaches a cosmetic that contains *Rhodiola*. However, the reference does not specifically teach adding the ingredient in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It

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would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

The reference also does not specifically teach adding all of the additional ingredients in claim 14. However, all of these ingredients are known in the art to be suitable for adding to a topical composition. Therefore, a person of ordinary skill in the art would have been motivated to add these ingredients to the composition taught by the combination of the references.

The reference does not specifically teach formulating the composition in the forms claimed by applicant in claim 15. These forms of administration are well known in the art to be acceptable forms for a topical composition. Based on this knowledge, a person of ordinary skill in the art would have had a reasonable expectation that formulating the composition taught by the reference in the claimed forms would be successful. Therefore, an artisan of ordinary skill would have been motivated to formulate the composition taught by the reference in the forms claimed by applicant.

12. Claims 1-5, 8, 9, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '840.

As stated above, US '840 teaches a cosmetic that contains coconut milk. However, the reference does not specifically teach adding the ingredient in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It

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would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

The reference also does not specifically teach adding all of the additional ingredients in claim 14. However, all of these ingredients are known in the art to be suitable for adding to a topical composition. Therefore, a person of ordinary skill in the art would have been motivated to add these ingredients to the composition taught by the combination of the references.

The reference does not specifically teach formulating the composition in the forms claimed by applicant in claim 15. These forms of administration are well known in the art to be acceptable forms for a topical composition. Based on this knowledge, a person of ordinary skill in the art would have had a reasonable expectation that formulating the composition taught by the reference in the claimed forms would be successful. Therefore, an artisan of ordinary skill would have been motivated to formulate the composition taught by the reference in the forms claimed by applicant.

13. Claims 1-5, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP '498.

As stated above, JP '498 teaches a topical composition that contains neem extract. However, the reference does not specifically teach adding the ingredient in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to

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employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

The reference also does not specifically teach adding all of the additional ingredients in claim 14. However, all of these ingredients are known in the art to be suitable for adding to a topical composition. Therefore, a person of ordinary skill in the art would have been motivated to add these ingredients to the composition taught by the combination of the references.

The reference does not specifically teach formulating the composition in the forms claimed by applicant in claim 15. These forms of administration are well known in the art to be acceptable forms for a topical composition. Based on this knowledge, a person of ordinary skill in the art would have had a reasonable expectation that formulating the composition taught by the reference in the claimed forms would be successful. Therefore, an artisan of ordinary skill would have been motivated to formulate the composition taught by the reference in the forms claimed by applicant.

14. Claims 1-9 and 11-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '308, JP '729, US '840, and JP '498.

As discussed above each of these references teaches using *Gynostemma*, *Rhodiola*, coconut milk, and neem extract to improve the skin. These references show that it was well known in the art at the time of the invention to use the claimed ingredients in skin care compositions. It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third

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composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Based on the disclosure by these references that these substances are used in hair care compositions, an artisan of ordinary skill would have a reasonable expectation that a combination of the substances would also be useful in creating a skin care composition.

Therefore, the artisan would have been motivated to combine the claimed ingredients into a single composition. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See In re Sussman, 1943 C.D. 518; In re Huellmantel 139 USPQ 496; In re Crockett 126 USPQ 186.

The references also do not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

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The references also do not specifically teach adding all of the additional ingredients in claim 14. However, all of these ingredients are known in the art to be suitable for adding to a topical composition. Therefore, a person of ordinary skill in the art would have been motivated to add these ingredients to the composition taught by the combination of the references.

The references do not specifically teach formulating the composition in the forms claimed by applicant in claim 15. These forms of administration are well known in the art to be acceptable forms for a topical composition. Based on this knowledge, a person of ordinary skill in the art would have had a reasonable expectation that formulating the composition taught by the reference in the claimed forms would be successful. Therefore, an artisan of ordinary skill would have been motivated to formulate the composition taught by the reference in the forms claimed by applicant.

15. Claims 1 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '308, JP '729, US '840, and JP '498 as applied to claims 1-9 and 11-16 above, and further in view of US Pat. No. 5,698,423.

As stated above, US '308, JP '729, US '840, and JP '498 teach the claimed composition. However, the references do not specifically teach using a neem seed culture in the composition. US '423 teaches that using a neem seed culture to create a pharmaceutical extract is beneficial over using a straight neem seed extract because it eliminates contaminants present in the straight seed extract (see column 4, lines 38-42). Based on this teaching, a person of ordinary skill in the art would have reasonably expected that the neem composition taught by JP '498 could be improved if it was created in the manner claimed by US '423. Therefore, an artisan of ordinary

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skill would have been motivated to use a neem seed extract created using a cell culture extract based on the teaching of US '423 that this method of extraction creates a superior product.

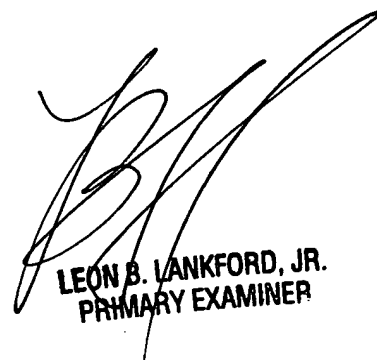
16. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (703) 306-5823. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Susan Coe, Examiner
May 2, 2003



LEON B. LANKFORD, JR.
PRIMARY EXAMINER

10/034, 36
FD=12/28/61

680.0049USU

WHAT IS CLAIMED IS:

1. (Amended) A skin composition, comprising:

at least one plant ingredient selected from the group consisting of *Gynostemma*, coconut water, *Azadiracta*, and *Rhodiola* present in an amount effective to improve the aesthetic appearance of skin; and

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a pharmaceutically or cosmetically acceptable vehicle, wherein when the plant ingredient is from *Azadiracta* seed, the composition further includes at least one other ingredient selected from the group consisting of *Gynostemma*, coconut water and *Rhodiola*.

2. The composition of claim 1, wherein the at least one plant ingredient is present in an amount about 0.0001 wt% to about 50 wt% of the total weight of the composition.

3. The composition of claim 1, wherein the at least one plant ingredient is present in an amount about 0.001 wt% to about 10 wt% of the total weight of the composition.

4. The composition of claim 1, wherein the at least one plant ingredient is present in an amount about 0.01 wt% to about 5 wt% of the total weight of the composition.

5. The composition of claim 1, wherein the at least one plant ingredient is present in an amount about 0.1 wt% to about 3 wt% of the total weight of the composition.

6. The composition of claim 1, wherein the at least one plant ingredient is *Gynostemma*.

↑ conflicts w/ claim 1
which states A2 is
a required ingredient

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7. The composition of claim 6, wherein *Gynostemma* is present in an amount about 0.001 wt% to about 10 wt% of the total weight of the composition.

5

8. The composition of claim 1, wherein the at least one plant ingredient is coconut water. - *conflict*

9. The composition of claim 8, wherein the coconut water is present in an amount about 0.001 wt% to about 10 wt% of the total weight of the composition.

10. The composition of claim 1, wherein the at least one plant ingredient is neem seed cell culture or its extract present in an amount about 0.001 wt% to about 10 wt% of the total weight of the composition.

11. (Amended) The composition of claim 1, wherein the at least one plant ingredient is *Rhodiola*.

A3
20

12. (Amended) The composition of claim 11, wherein *Rhodiola* is present in an amount about 0.001 wt% to about 10 wt% of the total weight of the composition.

13. (Amended) The composition of claim 1, wherein said plant ingredients are *Gynostemma*, coconut water, *Azadirachta* and *Rhodiola*.

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14. The composition of claim 1, wherein the vehicle is one or more ingredients selected from the group consisting of aqueous systems, glycerin, C₁₋₄ alcohols, fatty alcohols, fatty ethers, fatty esters, polyols, glycols, vegetable oils, mineral oils, liposomes, laminar lipid materials,

silicone oils, water, and any combinations thereof.

15. The composition of claim 1, wherein the composition is in a product form selected from the group consisting of an aerosol spray, cream, emulsion, solid, liquid, dispersion, foam, gel, lotion, mousse, ointment, powder, patch, pomade, solution, pump spray, stick, and towelette.

Q4 16. (Amended) The composition of claim 1, wherein the plant ingredient is selected from the group consisting of *Gynostemma*, coconut water, and *Rhodiola*.

17. A method of improving the aesthetic appearance of skin, hair and/or nails, comprising topically applying to the skin, hair and/or nail a cosmetically effective amount of the composition of claim 1.

18. The method of claim 17, wherein the improvement is at least one improvement selected from the group consisting of reduction in dermatological signs of chronological aging, hormonal aging and/or photo-aging; reduction in skin fragility; reduction in pore size; prevention and/or reversal of loss of collagen and/or elastin; ameliorating the effects of estrogen imbalance; prevention of skin atrophy; prevention and/or reduction in appearance of lines and/or wrinkles; prevention, reduction and/or treatment of hyperpigmentation; improvement in skin tone, radiance, clarity and/or tautness; prevention, reduction, and/or amelioration of skin sagging; promotion of anti-oxidant activity; improvement in skin firmness, plumpness, suppleness and/or softness; improvement in procollagen and/or collagen production; improvement in skin texture

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and/or promotion of retexturization; improvement in skin barrier repair and/or function; improvement in appearance of skin contours; restoration of skin luster and/or brightness; minimization of dermatological signs of fatigue and/or

5 stress; resistance to environmental stress; replenishment of ingredients in the skin decreased by aging and/or menopause; improved communication among skin cells; increase in cell proliferation and/or multiplication; increase in skin cell metabolism decreased by aging and/or menopause; retardation

10 of cellular aging; inhibition of enzymes in the skin that accelerate aging of skin cells; minimization of skin dryness and/or improvement in skin moisturization; minimization of

~~skin discoloration; promotion and/or acceleration of cell~~
turnover; enhancement of skin thickness; increase in skin

15 elasticity and/or resiliency; enhancement of exfoliation; prevention and reversal of loss of glycosaminoglycans, collagen and/or elastin; improvement in microcirculation; decrease and/or prevention in cellulite formation; and reduction in acne formation; and any combinations thereof.

20

19. The method of claim 17, wherein the improvement is at least one improvement selected from the group consisting of: reduction in dermatological signs of chronological

aging, hormonal aging and/or photo-aging; prevention and/or

25 reduction in appearance and/or depth of lines and/or

wrinkles; improvement in skin tone, radiance, clarity and/or tauntness; improvement in skin firmness, plumpness,

suppleness, and/or softness; and improvement in skin texture and/or promotion of retexturization; and any combinations

30 thereof.

20. The method of claim 17, wherein the improvement is at least one improvement selected from the group consisting

of minimization of dermatological signs of fatigue and/or stress; resistance to environmental stress; resistance to skin breakouts; resistance to pollution and/or temperature changes; minimization of skin dryness and/or improvement in
5 skin moisturization; increase in skin elasticity and/or resiliency; and ameliorating the effects on skin of pollution, skin breakouts, temperature changes and/or solar radiation; and any combinations thereof.

10 21. The method of claim 17, wherein said composition has *Gynostemma*, coconut water, *Azadiracta*, and *Rhodeola*.

15 22. A method of improving the aesthetic appearance of skin, hair and/or nails, comprising topically applying to the skin, hair and/or nail a cosmetically effective amount of the composition of claim 16.

20 23. The method of claim 22, wherein the improvement is at least one improvement selected from the group consisting of minimization of dermatological signs of fatigue and/or stress; resistance to environmental stress; resistance to skin breakouts; resistance to pollution and/or temperature changes; minimization of skin dryness and/or improvement in
25 skin moisturization; increase in skin elasticity and/or resiliency; ameliorating the effects on skin of pollution, skin breakouts, temperature changes and/or solar radiation; and any combinations.

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24. The method of claim 22, wherein the at least one plant ingredient is about 0.0001 wt% to about 50 wt% of the total weight of the composition.

25. A method of treating skin, hair and/or nail comprising topically applying to the skin, hair and/or nail the composition of claim 1 in an amount effective to
5 prevent, ameliorate, inhibit and/or reduce signs of dermatological aging.

26. The method of claim 25, wherein the signs of aging are associated with one or more from the group consisting of
10 fatigue, physiological stress, environmental stress, pollution, temperature changes, skin breakouts, solar radiation, and any combinations thereof.

27. The method of claim 26, wherein the signs of aging
15 are one or more signs selected from the group consisting of fatigue, physiological stress, and environmental stress.

28. The method of claim 26, wherein the signs of aging are associated with one or more signs selected from the
20 group consisting of pollution, skin breakouts, temperature changes, and/or solar radiation.

29. A method of treating stressed skin comprising topically applying to the skin an effective amount of the
25 composition of claim 1.

30. A method of treating stressed skin comprising topically applying to the skin an effective amount of the
30 composition of claim 16.